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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,598	04/27/2007	John E. O'Gara	59894US(49991)	3666
48990 7590 07/13/2011 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER LOEWE, ROBERT S				
ART UNIT		PAPER NUMBER		
1766				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/587,598

**Applicant(s)**

O'GARA, JOHN E.

**Examiner**

ROBERT LOEWE

**Art Unit**

1766

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 May 2011.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,8-16,20-34,36,52 and 53 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-3,8-16,20-34,36,52 and 53 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)  
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments/remarks, filed on 5/25/11, have been fully considered. Applicant's amendments have caused the obviousness double patenting rejections made in the previous Office action to be withdrawn as neither the copending Application 11/631,341 nor US Pat. 7,250,214 claim the feature that the surface concentration of R<sup>6</sup> is greater than about 1.0  $\mu\text{mol}/\text{m}^2$  as required by independent claim 1.

The previously relied upon prior art rejection of claims 1-4, 7, 8 and 30-34 to Motokawa et al. (*J. Chromatography A*, 2002, 961, 52-63) has been withdrawn owing to Applicants amendments. Specifically, Motokawa et al. does not teach or suggest that the surface concentration of R<sup>6</sup> is greater than about 1.0  $\mu\text{mol}/\text{m}^2$  as required by independent claim 1.

Regarding the prior art rejection of O'Gara (US Pat. 6,528,167) in view of Motokawa et al. (*J. Chromatography A*, 2002, 961, 52-63), Applicants argue that the Examiner has not shown how one of ordinary skill in the art would achieve selective cleavage and replacement of the surface groups so as to maintain a surface concentration of R<sup>6</sup> is greater than about 1.0  $\mu\text{mol}/\text{m}^2$  as required by independent claim 1. The silica monoliths taught by Motokawa et al. comprise surface Si-CH<sub>3</sub> and Si-OH (silanol) groups since they are prepared by reaction of methyltrimethoxysilane and tetramethoxysilane. Motokawa et al. teaches that surface modification is carried out on the surface silanol groups by continuously feeding a solution of octadecyldimethyl-*N,N*-diethylaminosilane under a pressure of 50 mbar at 60 degrees C for 3 hours (experimental section). The result is the replacement of the surface silanol groups with an octadecyl dimethylsiloxy group. O'Gara teaches that the surface Si-CH<sub>3</sub> groups of the hybrid silica particles can be selectively converted to Si-F groups, then Si-OH groups. O'Gara further teaches surface modification with C<sub>18</sub> groups (columns 15 and 16). Applicants argue that Motokawa et al. does not teach selective cleavage and replacement of surface groups. However, given the combined teachings of O'Gara and Motokawa et al., a person having ordinary skill in the art would understand that any surface modifications which are taught to take place in O'Gara would out of necessity be performed in the manner taught by Motokawa et al., that is, by continuously feeding in the specific reactants into the hybrid silica monolith. Both the instant

specification and O'Gara describe the selective cleavage and replacement of surface groups. The transformations taught in the instant specification and in O'Gara are selective in that only chemically accessible Si-CH<sub>3</sub> groups on the surface of the hybrid silica particle or monolith react with the various reagents added thereto. This is true whether the system is a hybrid silica particle or a hybrid silica monolith. Therefore, it is submitted that the combined teachings of O'Gara in view of Motokawa et al. provide motivation for a person having ordinary skill in the art to prepare hybrid silica monoliths using the chemistry taught by Motokawa et al. and further provides a person having ordinary skill in the art the chemical tools and procedures to carry out the selective chemical transformations using the reagents taught by O'Gara in the manner taught by Motokawa et al. That is to say, feeding the respective chemicals through the hybrid silica monolithic columns would enable the reaction between chemically accessible surface Si-CH<sub>3</sub> groups, which amounts to the surface Si-CH<sub>3</sub> groups. Internal Si-CH<sub>3</sub> groups are not accessible and are therefore not prone to reaction. This is true whether these groups are present within hybrid silica particles or within hybrid silica monoliths since the silica particles themselves serve as the precursors to prepare the silica monoliths. In order to prepare a hybrid silica monolith one must first proceed through discrete hybrid silica particles. Therefore, Applicants arguments regarding the prior art rejection of O'Gara in view of Motokawa et al. are not found to be persuasive.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 8-16, 20-34, 36, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Gara (US Pat. 6,528,167) in view of Motokawa et al. (*J. Chromatography A*, **2002**, 961, 52-63).

Claims 1 and 52: O'Gara teaches and claims hybrid particles for chromatographic separations, wherein said particles have an interior and exterior surface, wherein the particles have the same claimed composition regarding Formula I of claim 1. O'Gara further teaches that the surface concentration of  $R^6$  is greater than about  $1 \mu\text{mol}/\text{m}^2$  (claims 19-22). O'Gara does not teach that the hybrid particles may be converted to porous monoliths. However, Motokawa et al. teaches porous inorganic/organic hybrid silica monoliths for chromatographic separations (abstract). O'Gara and Motokawa et al. are combinable because they are from the same field of endeavor, namely, preparation of hybrid organic/inorganic stationary phases for column chromatography. At the time of the invention, a person having ordinary skill in the art would have found it obvious to convert the hybrid particles as taught by O'Gara into hybrid porous monoliths as taught by Motokawa et al. and would have been motivated to do so since Motokawa et al. teaches that monolithic silica columns afford much lower separation impedance and higher permeabilities than particle-packed columns. Motokawa et al. also teaches that employment of columns based on small particles requires high-pressures which is difficult to achieve for conventional HPLC instrumentation (Introduction).

Instant claim 52 is a product-by-process claim. For such claims, patentability is based on the product itself, and not on its method of production. Therefore, it is submitted that Motokawa et al. provides motivation to prepare silica monoliths using the compositions as taught by O'Gara. A person having ordinary skill in the art would be cognizant of maintaining/preserving the attractive physical property limitations as taught by O'Gara, namely, the specific pore volumes, average pore diameters, specific surface areas and surface concentration of the  $R^6$  groups. Therefore, a person having ordinary skill in the art would have found it obvious to prepare silica-based monoliths having the claimed physical properties as taught by O'Gara. As such, there would not be expected to be substantial differences in structure of the claimed silica monoliths as compared to the silica monoliths which is suggested by the combination of O'Gara in view of Motokawa et al.

Since many of the remaining dependent claims of O'Gara are identical to those as claimed, a summary showing which claims read on the claims of O'Gara is shown below.

Claims 2 and 3 of O'Gara are identical or substantially identical to instant claims 2 and 3, respectively.

Claim 8: Claim 17 of O'Gara is identical to instant claim 8.

Claims 10-16: Claims 9-12 of O'Gara are identical or substantially identical to instant claims 10-16.

Claims 20-22: Claims 20-22 of O'Gara are identical or substantially identical to instant claims 20-22.

Claims 23-33: Claims 25-35 of O'Gara are identical or substantially identical to instant claims 23-33.

Claim 34: O'Gara teaches that the inorganic/organic hybrid particles have chromatographically-enhancing pore geometry (17:18-20).

Claim 36: It is submitted that the combination of O'Gara in view of Motokawa et al. renders obvious Applicants claimed method for preparing the porous hybrid inorganic/organic silica monoliths of instant claim 1. Specifically, given the motivation to prepare silica monoliths as taught by Motokawa et al., a person having ordinary skill in the art would follow the basic procedure as taught by Motokawa et al. Specifically, Motokawa et al. teaches preparing a monolithic material by preparing (1) an aqueous solution of starting silanes (which given the teachings of both O'Gara and Motokawa et al. includes employing TMOS and MTES starting materials) which further comprises surfactant (PEG) and an acidic catalyst (acetic acid, for example), followed by (2) stirring, and (3) placement into a capillary tube where it further reacts and is aged to produce a monolith material. The resulting monolith is then subjected to water and methanol washes. It should be noted that the column is treated with an aqueous basic solution. Therefore, the first water wash constitutes rinsing the monolith material with an aqueous base. It is clear from the teachings of Motokawa et al. that the water wash may take place at elevated temperature since the final aging step of occurs at 120 degrees C. Washing the monolith with methanol constitutes a solvent exchange. Motokawa et al. further teaches drying the monolith. While Motokawa et al. does not explicitly teach that the material is dried at room temperature followed by drying at an elevated temperature under vacuum, it is submitted that a

person having ordinary skill in the art understands that only through elevated temperature and application of vacuum does one stand the highest chance of removing all volatiles from the monolith. Further, drying under both heat and vacuum expedites the time required to dry the monolith, which is a more economical way of preparing the final monolithic column. Last, the surface modifications to the monolith in such a way as to prepare surface-modified monolithic columns having the surface groups as taught by O'Gara could be achieved through feeding the respective chemicals which would cause the desired chemical transformations ( $\text{Si-CH}_3 \rightarrow \text{Si-F} \rightarrow \text{Si-OH} \rightarrow \text{Si-OR}$ ).

Claim 53: O'Gara prepares hybrid particles having surface silicon-alkyl groups (example 1). O'Gara further teaches replacing one or more surface silicon-alkyl groups with halo/fluoro groups and with hydroxyl groups (Scheme on columns 15 and 16 and Example 6). O'Gara further teaches further modification of the surface methyl group converted hybrid inorganic/organic particles with a substituted siloxane group followed by end-capping with a trialkylhalosilane (example 9). O'Gara further teaches that the surface concentration of  $\text{R}^6$  is greater than about  $1 \mu\text{mol/m}^2$  (claims 19-22). O'Gara does not teach that the hybrid particles may be converted to porous monoliths. However, Motokawa et al. teaches porous silica monoliths for chromatographic separations (abstract). O'Gara and Motokawa et al. are combinable because they are from the same field of endeavor, namely, preparation of hybrid inorganic/organic stationary phases for column chromatography. At the time of the invention, a person having ordinary skill in the art would have found it obvious to convert the hybrid particles as taught by O'Gara into the claimed porous monoliths and would have been motivated to do so since Motokawa et al. teaches that monolithic silica columns afford much lower separation impedance and higher permeabilities than particle-packed columns. Motokawa et al. also teaches that employment of columns based on small particles requires high-pressures which is difficult to achieve for conventional HPLC instrumentation (Introduction).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

Art Unit: 1766

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT LOEWE whose telephone number is (571)270-3298. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Loewe/  
Primary Examiner, Art Unit 1766  
11-Jul-11